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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,918	11/01/2001	Sinpei Nakata	KAS-157	3025

24956 7590 11/16/2005

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ALEXANDRIA, VA 22314

EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1743

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p>09/936,918</p>	<p><b>Applicant(s)</b></p> <p>NAKATA ET AL.</p>	
	<p><b>Examiner</b></p> <p>Lyle A. Alexander</p>	<p><b>Art Unit</b></p> <p>1743</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br/> Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/> Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|--|---|

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3,6 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last paragraph of claim 1 is not clear what steps are intended by "... analysis parameters ... ". What types of analysis parameters are intended ? Further " ... calculates, based on the stored ..." is not clear what type of calculation steps are performed. The claims " standard value" is vague and indefinite as to what this value is and how it is calculated. The claimed "accuracy management" is also vague and indefinite as to what steps/calculations are performed. The claimed "deviation" calculation is also vague and indefinite how this calculation is made.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6 and 8-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 5-288756 or JP 4-128657.

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JP 5-288756 teaches a system to automatically transferring various kinds of parameters from an automatic analyzer. The automatic analyzer is provided with a sample identifying means 3, a reagent identifying means 10, and communication means 30, 31, 32. A sample identifying code 4 and a reagent identifying code 11 are automatically read by the sample identifying means and the reagent identifying means, and transmitted to an external computer 29 by the communication means. It is so designed that a parameter related to the analysis determined by the reagent and such parameters as the concentration, calibration curve, etc., of a standard sample to be used for calibration or the like are taken into the automatic analyzer from the external computer 29.

JP 4-128657 teaches an automated analyzer coupled to a network to monitor the condition as that at the time of analysis. The output is returned to any of the devices on the network after treating the parameters to determining if the analytical conditions and the results of analysis are valid. A plurality of analytical devices 6 and 10 are connected to a computer(1) via telecommunication lines (5). The conditions for operating the analytical devices are stored in a transmission parameter table(4) of the computer (1). At the start of analysis the data is sent to their respective analytical devices. The respective analytical devices store the analytical conditions being sent at the start of analysis in the parameter tables(8) and (12), and carry out analysis under these conditions. After completion of analysis. the results of analysis and the contents of the parameter table are sent and

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stored in the computer(1) automatically or by the instructions of an analyzer.

The computer(1) stores the analytical results and parameters sent by the analytical devices 6 and 10 as a set. Thus, since the control of both the analytical results and the analytical conditions is simultaneously carried out, errors can be prevented and the reliability of data can be enhanced.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Fritchie et al.(USP 6,022,746).

See the appropriate paragraph of the 5/31/05 Office action.

In light of the above 35 USC 112 second paragraph issues, the invention is best understood as a method of monitoring reagents and their controls. The Office maintains all of these steps are performed by Fritchie et al.

### ***Response to Arguments***

Applicants' arguments filed 8/31/05 have been fully considered but they are not persuasive.

Applicant's remarks were convincing with respect to Bevirt et al. and that rejection has been vacated.

Applicants' state Fritchie et al. fail to teach the claimed "accuracy management" and subsequent deviation calculations. In light of the above 35 USC 112 second paragraph issues, it is not clear what is intended by these steps. As the claims are best understood, Applicants' teach a method of calibration of the controls which are met by Fritchie et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743



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